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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,526	04/30/2001	Gary Maurice Dull	627-325IP	2781

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 06/03/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/845,526

Applicant(s)

DULL ET AL.

Examiner

Venkataraman
Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,22-41,48-66 and 73-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16,22-41,48-66 and 73-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group IV where both X and X' are carbons in Paper No. 6 is acknowledged. Applicants' amendment to claims 1-3, 16,22, 25-27, 41,48, 51-53 66 and 73 as well as cancellation of claims 17-21, 42-47 and 67-72 in paper # 6 is also made of record.

Claims 1-16, 22-41, 48-66 and 73-75 are now pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16, 22-41, 48-66 and 73-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Claims 1, 16, 25, 41,51 and 66 recite the phrase "containing" in the definition of R' and R" (se aromatic ring –containing species) is indefinite as this term is open-ended and can include more than what is being positively recited therein. See MPEP 2111.03 which states under transitional phrases The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

Art Unit: 1624

2. Also in these claims the term "functionality" in the phrase "cycloalkyl functionality" is deemed as indefinite as it implies presence of functional group(s). Its replacement with group is suggested.
3. Claims 25-41 appears to be composition claims but as recited they are compound claims since they lack additional ingredients. Note a composition requires more than one ingredient. Appropriate correction is needed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-66 and 73-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating disorders associated with a dysfunction of nicotinic receptors, does not reasonably provide enablement for prevention of all or any disorders associated with nicotinic receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use of the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

Art Unit: 1624

1) The nature of the invention:

The method of use claim 6 is drawn to besides treatment, prevention of any and all disorders due to dysfunction of nicotinic receptors including those yet to be discovered. However, specification provides no support for preventing all or any disorders. In fact based on the specification and examples receptor binding, it appears that the instant compounds are mainly nicotinic receptor antagonist and may be useful for treating disorders wherein nicotinic receptor is implicated. Specification has not provided any evidence or nexus that because of the mode of action of the instant compound viz. nicotinic receptor antagonist, the compound would be useful for preventing all or any disorders.

2) The state of the prior art:

There are no known compounds of similar structure, which have been demonstrated shown to be useful for preventing all or any diseases. For example, the notion that a compound could be effective against all or any diseases because of its in interaction with a single target, in the instant case nicotinic receptor, in general is absolutely contrary to our current understanding of pharmacological basis of drug design and treatment of diseases. In fact a specific target is often chosen to treat a specific disease or that specific target related diseases. Indeed, applicants' instant claims 52-66 and 73-75 rely on this fact for treating disorders. Furthermore, the prior art search in the related area does not suggest that because of the mode of action of a compound, as nicotinic receptor antagonist would be useful for preventing disorders. For example,

Art Unit: 1624

Clementi et al. although discusses use of nicotinic receptor antagonist for treatment, does not suggest use for prevention.

3) The predictability or lack thereof in the art:

As noted above, although there several prior art which teach similar compounds as nicotinic receptor antagonist, they do not teach use of the compound disclosed for preventing any or all disorders and hence there is no art predictability or assurance that instant compound would do so.

4) The amount of direction or guidance present:

Specification provides no guidance or direction, as to how would one use the instant compound to prevent all or any disorder.

5) The presence or absence of working examples:

There are working examples to show that how the instant compound could be used to prevent disorders wherein nicotinic receptor is implicated as causative agent.

6) The breadth of the claim:

The breadth of the claim is broad enough to include prevention of any or all diseases including those yet to be discovered for which there is no pharmacological basis or showing in the specification.

7) The quantity of experimentation needed:

The quantity of experimentation needed would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan for the many reasons stated above.

Art Unit: 1624

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims 52-66 and 73-75.

Allowable Subject Matter

Claims 1-16, 22-41, 48-51 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action. Said claims would be allowed since specific species embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

References cited in the Information Disclosure Statement (paper # 4) are made of record.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Application/Control Number: 09/845,526

Page 7

Art Unit: 1624

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5/28/2002